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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/487,792	01/20/00	LAFLEUR D	PF482P1

HM22/0714

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville MD 20850

EXAMINER	
SCHNIZER,R	
ART UNIT	**PAPER NUMBER**
1632	8

DATE MAILED: 07/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

FILE COPY

Office Action Summary	Application No. 09/487,792	Applicant(s) Lafleur
	Examiner Richard Schnizer	Group Art Unit 1632

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-40* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-40* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, 17, 24, 25, 28-30, 32, 34-37, 39, and 40, drawn to nucleic acids and methods of use, classified in class 435, subclass 69.1.

II. Claims 14, 15, 18-21, and 38, drawn to a polypeptide, classified in class 530, subclass 350.

III. Claim 16, drawn to an antibody, classified in class 530, subclass 387.1.

IV. Claim 22, drawn to an agonist of unknown structure, classified in class 514, subclass 1.

V. Claim 23, drawn to an antagonist of unknown structure, classified in class 514, subclass 1.

VI. Claims 24, 29, 31, and 39, drawn to polypeptide therapy, classified in class 514, subclass 2.

VII. Claim 26, drawn to diagnosis based on polypeptide expression or activity, classified in class 514, subclass 2.

VIII. Claim 27, drawn to a binding assay, classified in class 435, subclass 7.1.

Claims 24, 29 and 39 are generic to a plurality of disclosed patentably distinct species. If a group containing any of these claims is elected, the generic claim or claims will be examined to the extent that it is defined by the classification of the elected group.

The inventions are distinct, each from the other because of the following reasons:

The polynucleotides of group I are related to the polypeptides of group II because the polynucleotides encode the polypeptides. The polynucleotides may be used for the heterologous production of the polypeptides in a host cell. However, these inventions are distinct because the polypeptide may be produced by another materially different process, such as *in vitro* synthetic organic chemistry. Further, the DNA may be used for methods other than the production of the protein, such as hybridization assays.

The polynucleotides of group I are related to the antibody of group III because the polynucleotides encode the cognate antigen. However the polynucleotides are not required for production of the antibody. Further, polynucleotides and antibodies are wholly different compounds with different compositions and functions.

The polynucleotides of group I are unrelated to the agonist and antagonist of groups IV and V. These compositions have different structures and functions and each has an independent utility that is distinct for each invention and which cannot be exchanged.

The polynucleotides of group I are unrelated to the methods of groups VI, VII and VIII. The polynucleotides cannot be used in, or made by, any of these methods.

The polypeptides of Group II are related to the antibodies of Group III by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the polypeptide can be used in another and materially different process from the use for production of the antibody, such as in an assay for the identification of antagonists which inhibit the activity of the polypeptide.

The polypeptides of group II are related to the agonist of group IV and the antagonist of group V because these molecules affect the activity of the polypeptide. The inventions are distinct because these compositions have distinct structures and functions. For example the agonist and antagonist have opposite effects on the activity of the polypeptide, and the polypeptide has a different activity than the agonist or the antagonist.

The polypeptides of Group II can be related to the inventions of Groups VI, VII, and VIII as a product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be used for the production of antibodies of Group III.

The antibody of group III is unrelated to the agonist and antagonist of groups IV and V. These compositions have distinct structures and functions. For example, the general structural

characteristics of the antibody are known, whereas the agonist and antagonist are hypothetical molecules of unknown structure. The antibody functions by binding the polypeptide of group I, however, the agonist and antagonist need not interact directly with the polypeptide.

The antibody of Group III is unrelated to the methods of Groups VI or VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibody of Group III is not made by or used in the methods of Groups VI or VII.

The antibody of group III is related to the binding assay of group VIII because it could be identified by the binding assay. The inventions are distinct because the binding assay could be used to identify other ligands of the polypeptide of group I, such as its receptor *in vivo*.

The agonist and antagonist of groups IV and V are related to each other in that they affect the same target molecule. They are distinct in that they have different structures and opposed functions.

The agonist and antagonist of groups IV and V are unrelated to the methods of Groups VI and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the agonist and the antagonist are not used in or made by the methods of Groups VI and VII.

The agonist and antagonist are relate to the binding assay of group VIII because they could conceivably be isolated by the binding assay. The inventions are distinct because the binding assay could be used to identify other ligands of the polypeptide of group I, such as its receptor *in vivo*.

The methods of Groups VI, VII, and VIII are distinct, each from the other, because they represent different inventive endeavors. The inventions of these groups represent separate and distinct methods with different starting materials, protocols, and outcomes.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

A telephone call was made to Jim Davis on 7/6/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday-Friday from 7:30 to 4:00 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasemine Chambers, can be reached at 703-308-2035. The FAX phone number for art unit 1632 is 703-308-0294.

Inquiries of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Richard Schnizer, Ph. D.

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER